# 510(k) Summary f Safety and Effectiveness

K020114

JUL 12 2002

(1) **Submitter's name:** Encore Orthopedics, Inc.
**Submitter's address:** 9800 Metric Blvd, Austin, TX 78758
**Submitter's teleph ne number:** (512) 834-6255
**Contact person:** Joanna Droege
**Date summary prepared:** April 11, 2002

(2) **Trade or proprietary device name:** 3D Knee
**Common or usual name:** Knee system
**Classification:** Class II
**Product Code:** JWH
**Classification Name:** Prosthesis, knee, patellofemorotibial, semiconstrained, cemented, polymer, metal, polymer

(3) **Legally marketed predicate device:** Foundation Knee System (K923277)
Lateral Pivot Insert (K000590)

(4) **Subject device description:**

The 3D Knee is comprised of a femoral and a tibial component. The femoral component is manufactured from CoCr alloy conforming to ASTM F75, is available in 6 sizes (2-12) and is provided in left and right configurations. The femoral component is designed to match the condyles of the tibial insert for greater congruency and is similar to the Foundation Knee cleared in K923277.

The 3D Knee tibial inserts are manufactured from ultra high molecular weight polyethylene (UHMWPE) that conforms to ASTM F648. The tibial inserts are available in 6 sizes (2-12) and 5 thicknesses (9-19) and are provided in right and left orientations. The tibial insert is similar in design to the Foundation Lateral Pivot Insert cleared in K000590. This insert is intended to more closely complement the kinematics of the resurfaced knee, allowing rotation about the lateral condyle and increased congruency of the lateral condyle. The baseplate attachment mechanism is the same as the previously cleared Foundation Knee System inserts; therefore, the attachment strength is the same.

(5) **Subject device intended use:**

This device is part of a total knee replacement system utilized in treating patients who are candidates for primary cemented total knee arthroplasty or revision arthroplasty where bone loss is minimal and the collateral ligaments are intact. It is intended to aid the surgeon in relieving the patient of knee pain and restoring knee joint function.

(6) **Risk Summary:**

Conditions presenting an increased risk of failure include:

- infection (or a history of infection), acute or chronic, local or systemic;
- insufficient bone quality which may affect the stability of the implant;
- muscular, neurological or vascular deficiencies, which compromise the affected extremity;
- obesity;
- alcoholism or other addictions;
- materials sensitivity;
- loss of ligamentous structures;
- high levels of physical activity (e.g. competitive sports, heavy physical labor)

(7) **Testing:**

Clinical Testing: Clinical testing was not used to determine substantial equivalence.

Non-clinical Testing: Mechanical analysis was completed to determine substantial equivalence.

(8) **Basis for Substantial Equivalence:**

The 3D Knee is similar in design, materials and indications to the Foundation Knee System (K923277) and the Lateral Pivot Insert (K000590).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2002

Joanna Droege
Regulatory/QA Engineer
Encore Orthopedics, Inc.
9800 Metric Boulevard
Austin, TX 78758

Re: K020114
Trade/Device Name: 3D Knee
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: April 11, 2002
Received: April 15, 2002

Dear Ms. Droege:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020114

K020114

Device Name: 3D Knee

Indications For Use:

## 3D Knee
## Indications For Use

This device is part of a total knee replacement system utilized in treating patients who are candidates for primary cemented total knee arthroplasty or revision arthroplasty where bone loss is minimal and the collateral ligaments are intact. It is intended to aid the surgeon in relieving the patient of knee pain and restoring knee joint function.

- Noninflammatory degenerative joint disease including osteoarthritis or traumatic arthritis
- Avascular necrosis of the femoral condyle
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
- Moderate valgus, varus or flexion deformities
- Rheumatoid arthritis
- Treatment of fractures that are unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020114

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)_

Jun 27, 02

OR/CDRH/ODE/DGRND

OR

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